

Remarks/Arguments:

The pending claims are 10-28.

Introduction

The invention claimed herein is a stent (claims 10-21) and the method of using such a stent (claims 22-28), characterized by a tubular construction, comprising a plurality of adjacent hoops that are aligned along the tubular axis. Each hoop comprises a series of elongate elements which meet one another and form vertices. At least some of the vertices axially abut and are connected to oppositely pointed vertices of an adjacent hoop. Each hoop is separate and distinct from the other hoops. There is also a graft that closes the openings of the stent structure. Claim 17 is indicated to be directed to patentable subject matter.

A. **Summary of Pending Rejections**

In the Office Action of August 15, 2003, claims 12 and 19-20 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,360,443 to Barone et al. in view of U.S. Patent No. 5,035,706 to Gianturco et al. (hereinafter "Gianturco"). During a telephone Interview on October 14, 2003 between Examiner Bui and applicant's representative Stanley Weinberg, the Examiner acknowledged that the Statement of Rejection was incorrect. It should have read, instead, as rejecting claims 10-11, 13-15, 16, and 18-21 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,360,443 to Barone et al. in view of U.S. Patent No. 5,035,706 to Gianturco.

As a result of the October 14, 2003 interview, a new Office Action issued on October 21, 2003, superceding the August 15 action and setting a new date for response. The new Office Action rejected claims 10-11, 13-15, 16, and 18-21 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,360,443 to Barone et al. in view of U.S. Patent No. 5,035,706 to Gianturco.

In addition to the above rejection, claim 12 was rejected under 35 U.S.C. § 103(a) as unpatentable over Barone in view of Gianturco '706 and further in view of U.S. Patent No. 4,503,569 to Dotter; claims 22-23, 25-26, and 28 were rejected under 35 U.S.C. § 103(a) as unpatentable over Barone in view of Gianturco '706 and further in view of U.S. Patent No. 4,580,568 to Gianturco; and claims 24 and 27 were rejected under 35 U.S.C. § 103(a) as

unpatentable over Barone and Gianturco '706 in view of Gianturco '568 and further in view of Dotter.

Claims 10-12 and 18-19 were also rejected for obviousness-type double patenting over U.S. Patent No. 5,683,448 and U.S. Patent No. 6,174,328.

B. Response to Double-Patenting Rejection

Responsive to the double patenting rejection, submitted herewith is a Terminal Disclaimer To Overcome Double Patenting Rejection disclaiming the terminal part of the statutory term of any patent granted on this application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §§ 154, 155, 156 and 173 of United States Patent No. 5,683,448 and United States Patent No. 6,174,328. However, Applicant does not concede that the claims presently applied for are necessarily obvious in view of the cited references. With the filing of this Terminal Disclaimer, the pending rejection should be withdrawn.

C. Response to Rejections Under 35 U.S.C. § 103

1. The Rejection of Claims 10-11, 13-16 and 18-21

The rejection of claims 10-11, 13-16 and 18-21 under 35 U.S.C. § 103(a) as unpatentable over Barone et al. (U.S. Patent No. 5,360,443) in view of Gianturco (U.S. Patent No. 5,035,706) is respectfully traversed.

Claim 10 recites, in part,

a plurality of separate and distinct hoops aligned adjacent one another along the axis of said tubular stent, each of said separate and distinct hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the axis of the stent, wherein at least some of said vertices axially abut.

Page 3 of the Office Action acknowledges that Barone et al. does not disclose a stent structure having separate and distinct hoops. Consequently, page 4 of the Office Action contends that it would have been obvious to replace the stent structure in Barone with the stent configuration shown in Figure 6 of Gianturco. The cited art, however, lacks any suggestion for

this substitution of structures and the Examiner has cited none. Clearly the present disclosure is the source of this combination.

Moreover, Figure 6 of Gianturco does not disclose or suggest the stent structure recited in claim 10. Page 3 of the Office Action has misinterpreted Figure 6 of Gianturco. Page 3 of the Office Action contends that Figure 6 of Gianturco shows "a stent having separate and distinct hoops and vertices connected together in a manner as recited in the claims." Contrary to this assertion, Figure 6 of Gianturco shows a three-segment stent: the first segment is segment 10'''; the second segment is segment 16'; and the third segment is segment 16".

The ends on the left side of segment 10''' have rounded eyes, not vertices. The ends on the right side of segment 10''' have rounded eyes, not vertices. The ends on the left side of segment 16' have eyes, not vertices. Moreover, the eyes on the right side of segment 10''' and the eyes on the left side of segment 10''' are not "meeting one another and forming vertices axially pointing in a direction along the axis of the stent" as recited in claim 10. Instead, the eyes are alongside each other. In addition, none of these eyes "axially abut." Instead, they are joined at their sides.

The right ends of segment 16' have hooks. (col. 4, lines 50-51). The left ends of segment 16" have eyes. Even assuming (without conceding) that the hooks on the right ends of segment 16' may be considered to be vertices, the eyes on the left ends of segment may not be considered to be vertices. Therefore, these hooks and eyes are not "meeting one another and forming vertices axially pointing a direction along the axis of the stent." (emphasis added). In addition, the hooks on the right ends of segment 16' enter into the eyes on the left side of segment 16". None of the hooks and eyes "axially abut."

To establish a prima facie case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. As shown above, Gianturco does not disclose or suggest all of the features recited in claim 10. Since the Office Action admits that Barone et al. does not disclose all of the features recited in claim 10, and since Gianturco does not disclose or suggest those not shown by Barone and none of the cited art suggests any combination of the features in these two references, it necessarily follows that the combination of the two references does not disclose or suggest all of them. Accordingly, for these reasons alone, claim 10 is not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Barone et al. in view of Gianturco.

Claims 11, 13-16 and 18-21 depend from claim 10. Since claim 10 is not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Barone et al. in view of Gianturco, dependent claims 11, 13-16 and 18-21 are also not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Barone et al. in view of Gianturco. Applicant therefore respectfully submits that this rejection should be withdrawn on this basis above, although there may be other reasons these claims are separately patentable .

2. The rejection of claim 12

The rejection of claim 12 under 35 U.S.C. § 103(a) as unpatentable over Barone in view of Gianturco '706 and further in view of U.S. Patent No. 4,503,569 to Dotter is respectfully traversed. Claim 12 depends from claim 10. As shown above, Barone et al. and Gianturco do not disclose or suggest certain important features recited in claim 10.

Dotter adds nothing to the teachings of Barone and Gianturco. Rather, it discloses only a coil-type stent with no elongate elements forming vertices. More specifically, Dotter does not disclose or suggest "vertices axially pointing in a direction along the axis of the stent." As indicated above, Dotter actually includes nothing which may be characterized as vertices. What appear to be "vertices" in Dotter's two dimensional drawings (and the apparent basis for citing Dotter) point in a direction that is orthogonal to the axis of the stent. Second, Dotter does not disclose or suggest any vertices which axially abut one another, and, of course, Dotter does not disclose or suggest "at least some of said vertices. . .are individually connected to oppositely pointed vertices of elongate members of an adjacent hoop." Fourth, and most importantly, Dotter does not show or suggest separate and distinct hoops. Therefore, claim 10 is not anticipated or suggested by Dotter in whole or in part. Nor does Dotter remedy the deficiencies of Barone and Gianturco Discussed above. For all of these reasons, applicant therefore contends that this rejection should also be withdrawn.

3. The rejection of claims 22 and 28

The rejection of claims 22 and 28 under 35 U.S.C. § 103(a) as unpatentable over Barone in view of Gianturco ('706) and further in view of Gianturco U.S. Patent No. 4,580,568 is respectfully traversed.

Claim 22 is a method claim and claims 23-28 are dependent on claim 22. Step a. in claim 22 recites "providing a stent-graft combination as recited in claim 10." As shown above, the stents in Barone and in Gianturco ('706) do not disclose or suggest the stent as now recited in claim 10. Since step a. in claim 22 incorporates claim 10 by reference, Barone in combination with Gianturco does not disclose or suggest step a. Claim 22 and the claims dependent on claim 22 should be patentable for this reason alone.

Gianturco '568 does not remedy this deficiency in Barone et al. and Gianturco ('706) because it also does not disclose or suggest a stent as recited in claim 10. Gianturco '568 is cited in the Office Action only to show a self-expanding stent used in a stent graft. As noted above, to establish a prima facie case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Neither Gianturco '568 nor the combined Barone and Gianturco '706 disclose or suggest all of the features recited in claim 10. Accordingly, neither claim 22 nor any claim dependent thereon is subject to rejection under 35 U.S.C. § 103(a) over the Barone, Gianturco '706, Gianturco '568 combination. Nor does Dotter, added with regard to claims 24 and 27 to show a self expanding stent, remedy this deficiency. Withdrawal of this rejection is therefore respectfully requested.

D. Response to Objection to Claim 17

Applicant acknowledges with thanks the Examiner's indication that claim 17 is objected to as being dependent upon a rejected base claim, but that it would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant has not rewritten claim 17 because claims 16 and 10 upon which claim 17 is dependent are, applicant contends, clearly patentable for the reasons set forth above.

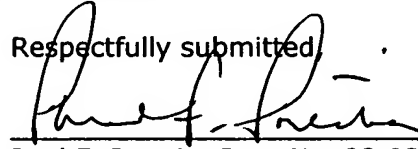
Appln. No.: 10/087,320
Amendment Dated January 21, 2004
Reply to Office Action of October 21, 2003

BSI-030US7

E. Summary

For all of the foregoing reasons, applicant contends that all pending claims are in condition for allowance and early notification thereof is respectfully requested. The Examiner is requested to call one of Applicant's undersigned attorneys if any question remains or if it appears that some further amendment is necessary for allowance.

Respectfully submitted,



Paul F. Prestia, Reg. No. 23,031
Stanley Weinberg, Reg. No. 25,276
Attorneys for Applicant

SW/pb

Dated: January 21, 2004

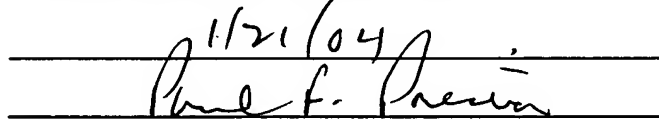
Valley Forge, PA 19482

P.O. Box 980

610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

1/21/04


PCBOCELL_I:\BSI\030US7\AMEND03.DOC